DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington, DC 20204

September 19, 2002

Michael F. Jacobson, Ph.D.
Center for Science in the Public Interest
1875 Connecticut Avenue, N.W.
Suite 300
Washington, D.C. 200009-5728

Re: GRAS Notice No. GRN 000091
Re: Food Additive Petition FAP 6A3930

Dear Dr. Jacobson:

The Food and Drug Administration (FDA) is responding to the letter dated August 12, 2002, that you sent to Dr. Lester Crawford regarding mycoprotein, an ingredient that is manufactured by Marlow Foods Ltd. (Marlow). Marlow recently informed FDA of its view that the use of mycoprotein in foods, primarily as a substitute for meat, is generally recognized as safe (GRAS) (GRAS Notice No. GRN 000091). Although Marlow is now marketing mycoprotein on the basis that the use is GRAS, mycoprotein is also the subject of a food additive petition (FAP 6A3930) that was filed by FDA in 1986.

In letters dated February 28, 2002, April 24, 2002, and June 5, 2002, you raised issues concerning Marlow's determination that the use of mycoprotein is safe and informed FDA that you had received complaint reports from 19 individuals who had experienced adverse reactions after consuming foods that contained mycoprotein. In your August 12 letter, you inform FDA that you have received a total of 33 reports from people living in the U.S. and overseas who had consumed mycoprotein. On August 23 and August 27, 2002, you provided copies to FDA of over 200 reports from people living in the U.S. and overseas who had consumed mycoprotein. In your June 5 and August 12 letters, you urge the FDA to deny Marlow's food additive petition and reject the company's GRAS determination in light of these reports.

In letters dated April 24, 2002, June 6, 2002, and July 24, 2002, we noted that we were considering your previous letters as comments to FAP 6A3930. We also informed you that we would send a letter to Marlow informing them of a change in the agency's conclusions about Marlow's determination that the use of mycoprotein in foods is GRAS if circumstances warranted.

We are carefully reviewing the reports that you have sent to us, and are considering them as comments to FAP 6A3930. As part of our review, we would like additional information pertaining to these reports. As you are aware, the Center for Food Safety and

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Applied Nutrition (CFSAN) collects information on adverse events from food products. In order to help us evaluate the significance of such adverse event reports, we believe we should obtain information directly from the consumer or their health care provider. Therefore, we would need to establish direct contact with some of the individuals who reported the adverse events to CSPI. Accordingly, because you have had contact with these individuals, we would appreciate receiving from you the names, addresses, and telephone numbers of those consumers who would be willing to be contacted directly by FDA, so that we may follow up on leads that may help resolve any outstanding issues.

Sincerely,

Alan M. Rulis, Ph.D.
Director
Office of Food Additive Safety
Center for Food Safety
and Applied Nutrition